



UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/295,691 04/21/99 KAYYEM

J A-67465/RFT/

EXAMINER

IM52/0911

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ART UNIT

PAPER NUMBER

10

1743
DATE MAILED:

09/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/295,691

Applicant(s)

Don Faiz Kayyem

Examiner

J. STARSIK

Group Art Unit

1743

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 19 June 2001.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 3, 5-7, 9-19, 21, 23-25, and 27-35 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3, 5-7, 9-19, 21, 23-25, and 27-35 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 7
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1743

DETAILED ACTION

Drawings

The proposed additional sheets of drawings, filed on June 19, 2001 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(a)(6) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of the structural organization of the elements illustrated in the drawings.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cell handling module recited in claims 1 and 19, the cell lysis module recited in claims 5 and 23, the cell removal module recited in claims 6 and 24, the cell concentration module recited claims 8 and 26, the separation module recited in claims 9 and 27, the electrophoresis module recited in claims 10 and 28, the reaction module recited in claims 11 and 29, the nucleic acid amplification module in claims 12 and 30, the thermal module recited in claims 13 and 31, the pump recited in claims 14 and 32, the electroosmotic pump recited in claims 16 and 33, and the valve recited in claims 17 and 34 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Art Unit: 1743

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 and 23-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Despite the length of the specification (i.e. 113 pages) very little of the specification is directed to the structure of the present invention (i.e., bulk of the specification is directed to the chemistry of the detector). The only reference to figures IA-!D is in the brief description of the drawings. In the portion of the specification directed to the present invention mainly consists of a long list elements such as sample lysis modules, cell concentration modules, etc., which embodiments of the present invention may contain. However the applicant fails to describe or illustrated the detail structure of most of these elements and more importantly the description of the invention fails to recite the structural organization of these elements. In conclusion, the specification recites a catalog of potential elements of the present invention without describing a single complete operative embodiment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1743

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5-7, 9-17, 19, 21, 23-25, and 27-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the applicant recites, "at least one well port". In order to recite "at least one well port" at least one well must be recited. In claim 1 as originally filed the applicant recited "a sample handling well". However, this recitation was removed by amendment. In claim 3 the applicant recites, "further comprising a reagent storage well". There is no recitation of any structural relationship(s) between the reagent storage well and the elements recited in claim 1. In claims 5, 6, 7 and 9 the applicant recites, "said cell handling module comprises a cell lysis module", "said cell handling module comprises a cell removal module", "said cell handling module comprises a cell concentration module", and "said sample handling module comprises a separation module", respectively. These claims are indefinite because there is not recitations of structure. The applicant is merely reciting different functions for the cell handling module. In other words there is no structure recited in claims 5, 6, 7 and 9 than there is in claim 1. What are the structural differences between "a cell lysis module" and "a cell concentration module" for example ? In claim 11 the applicant recites, "further comprising a reaction module". The applicant fails to recite and structural relationship(s) between the "reaction module" and the elements recited in claim 1. In claim 13, the applicant recites, "said reaction module". There is no

Art Unit: 1743

antecedent basis for this recitation in claim 1. In claim 14, the applicant recites, "further comprising a pump". The applicant fails to recite any structure relationship(s) between the pump and the elements recited in claim 1. In claim 18 the applicant recites, "f) a pump". This recitation is indefinite for two reasons. First, there are no structural relationships recited between the "pump" and the other elements recited in claim 18. Second, the pump is recited as part of the solid support. From the limited disclosure of the present invention the pump does the appear to be a feature of the solid support. Claims 21,23-25, 27,29, 31, and 32 are rejected for the same reasons as claims 3, 5-7, 9, 11, 13, and 14. The remaining claims are rejected because they depend on at least one of the above claims.

Response to Arguments

Applicant's arguments filed June 19, 2001 have been fully considered but they are not persuasive.

The applicant's remarks directed to the objection to the drawings are not well-taken for the following reasons. First, the proposed new drawings which have been disapproved illustrate none of the elements because they are illustrated as black boxes (nothing but circles and rectangles). Second, the applicant's remark that the proposed new drawings do not constitute new matter is incorrect. While some limited features in the proposed new drawings are supported by the application as originally filed the vast majority of the features is not. For example, the specification is devoid of the structural organization of elements recited in the proposed new

Art Unit: 1743

drawings. Applicant's remarks directed to the rejection under 35 U.S. C. 112, first paragraph are not well-taken for the following reasons. First, most of applicant's remarks are based on the assumption that the proposed new drawings would be approved. In the specification as originally filed the detailed description of the invention is devoid of any reference(s) to the drawings. Second, while there are references to U.S. Patents for some of the elements described in the specification and recited in the claims, there are many elements without references to U.S. Patents for the details of the element(s). For example there are not reference of any kind for the details of the cell concentration module or the cell removal module. The applicant's remarks directed to the lack of structural relationships between elements of the invention in the specification as originally filed are no well-taken because they are based entirely on the proposed new drawings, which are new matter. In other words, the applicant fails to point out where any structural relationships are recited in the specification as originally filed. Finally, the applicant's remarks directed to the rejections of the claims under 35 U.S.C., second paragraph are moot in view of the new rejections which are the result of applicant's amendments to the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1743

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (703) 308-1797. The examiner can normally be reached on Monday to Wednesday from 8:00 AM to 3:30 PM and on Thursday and Friday from 8:00 AM to 12:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3559.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


John S. Starsiak Jr.

06 September 2001


Jill Warden
Supervisory Patent Examiner
Technology Center 1700